

REMARKS

Claims 1-8 and 11-18 are pending.

Claims 9-10 have been cancelled.

To the extent that it is not necessary to address particular items within the Office Action in order to provide a complete response, Applicant's choice not to discuss such items is not, and cannot be interpreted as, acquiescence by the Applicant to such items, nor does it or can it be construed to limit the scope of any claims that may eventually issue in this patent application or any patent application claiming priority to this one.

A new drawing sheet is included with this Office Action, containing a single figure, Figure 5A. Figure 5A is merely the anastomosis tool of Figure 5 shown with its clamps holding tissue structures and its clips holding the tissue flaps created in ends of those tissue structures. Support for Figure 5A may be found in the specification at, for example, page 8, line 5 through page 9, line 4.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 1-8 and 11-18

Claim 1 has been amended to claim a "tool for performing end-to-end anastomosis between a first tissue structure and a second tissue structure each having at least two flaps at one end, comprising: a first clip configured to hold at least one flap of the first tissue structure; a second clip configured to hold at least one flap of the second tissue structure;

wherein said clips are movable from a first position spaced apart from one another to a second position closer to one another in which each flap held by said first clip abuts a corresponding flap held by said second clip; and at least one connector deployer oriented to deploy at least one connector completely through at least one of two abutting flaps.”

Shichman

U.S. Pat. No. 5,011,487 to Shichman (“Shichman”) neither discloses nor suggests each and every element of claim 1. Shichman neither expressly nor inherently describes clips configured to hold flaps of tissue structures. Instead, Shichman discloses a vascular clamp that merely closes upon a single blood vessel to occlude the flow of blood through it. (e.g., Figures 3-4; col. 5, lines 6-9; col. 7, lines 1-9). Those clamps hold the blood vessel, not flaps at an end of the blood vessel. (*Id.*) Further, nowhere does Shichman suggest “at least one connector deployer oriented to deploy at least one connector completely through two abutting flaps.” Instead, Shichman teaches a clamp assembly for use with a single blood vessel, and discloses no mechanism that could connect two separate blood vessels to one another.

Applicant does not acquiesce in the statement in the Office Action that “[e]ach of the two clamps has a first arm (40) and a second arm (42) and is configured to hold tissue flaps.” Shichman neither expressly nor inherently discloses flaps at the end of a tissue structure, or any structure or mechanism for holding such flaps. As shown in Figure 1, Shichman merely discloses a clamp assembly for holding a single blood vessel 54 for “temporary vascular occlusion” during microsurgery. (e.g., Figure 1; col. 1, lines 10-12; col. 2, lines 45-46).

Applicant also does not acquiesce in the statement in the Office Action that “when each clamp holds a vessel, the flap is attached to that vessel, therefore the clamp holds the flap, too.” First, as described above, Shichman does not disclose any structure or mechanism for holding a flap at the end of a tissue structure. Second, where a structure has multiple

parts, holding one part of that structure does not constitute holding the other. That is, where a structure A has components B and C, holding B is not the same as holding C, because B and C are separate entities. To put it another way, when Grandma grabs little Johnny's ear and squeezes to pull him away from the Christmas cookies, she is not holding his hand, even though the ear and the hand are both part of Johnny.

Thus, Shichman neither expressly nor inherently describes each and every element claimed in claim 1, and Applicant believes claim 1 is in condition for allowance. Claims 2-8 and 15-17 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With respect to canceled claim 9, Applicant does not acquiesce in the characterization of the post 116 of Shichman as a clip. The post 116 is a "suture tie post 116" having a suture receiving slot 120 defined therein. (e.g., Figure 1; col. 7, lines 30-40). Shichman discloses nothing that would even suggest that the member 118 of the suture tie post 116 could be movable relative to one another, or that they could clip anything at all, even suture; rather, suture may be "wedged into the receiving slot 120." (col. 7, lines 48-50).

With respect to claim 17, Applicant does not acquiesce in the characterization of the claimed finger as human tissue. Rather, the finger is a structure that is part of the tool. (e.g., page 10, line 9 through page 11, line 9). Applicant does not, and indeed cannot, claim human tissue.

Green

U.S. Pat. No. 5,158,567 to Green ("Green") neither discloses nor suggests each and every element of claim 1. Green neither expressly nor inherently describes clips configured to hold flaps of tissue structures, much less clips movable relative to one another. The items 13 characterized as "clamps" in the Office Action are instead stapling assemblies. (e.g., col. 2,

lines 23-27). Nowhere does Green expressly or inherently describe any structure on the stapling assemblies that could be used to clamp anything, much less clips configured to hold flaps of tissue structures. Further, Green neither expressly nor inherently discloses “at least one connector deployer oriented to deploy at least one connector completely through two abutting flaps.” Rather, Green discloses stapling assemblies 13 that are expressly limited to entering a layer of tissue without penetrating it completely. (*e.g.*, Figures 7-10 (note tissue layer 12); col. 5, lines 27-29; col. 6, lines 9-14).

Thus, Green neither expressly nor inherently describes each and every element claimed in claim 1, and Applicant believes claim 1 is in condition for allowance. Claims 10-14 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

Goldstein

U.S. Pat. No. 4,635,636 to Goldstein (“Goldstein”) neither discloses nor suggests each and every element of claim 1. Goldstein neither expressly nor inherently describes clips configured to hold flaps of tissue structures. Rather, Goldstein discloses microspikes 66, 68 configured to penetrate “only the adventitia of the duct or vessel.” (*e.g.*, Figure 2; column 5, lines 23-28). Thus, the tissue structure is not clipped; rather, it is penetrated by spikes. Further, Goldstein nowhere discloses any structure, spikes or not, for holding flaps of tissue structures.

In addition, Goldstein neither expressly nor inherently discloses “at least one connector deployer oriented to deploy at least one connector completely through two abutting flaps.” Rather, Goldstein simply discloses two clamps 30 for holding and approximating tissue structures. (*e.g.*, Figure 1; col. 4, lines 28-44). No connectors, or mechanisms for deploying them, are disclosed anywhere in Goldstein.

Thus, Goldstein neither expressly nor inherently describes each and every element claimed in claim 1, and Applicant believes claim 1 is in condition for allowance. Claims 3, 4, 6 and 15-18 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



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